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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,555	10/31/2003	Roland Christof Hutter	21686-US	9951
22829 7590 08/27/2007 ROCHE MOLECULAR SYSTEMS INC PATENT LAW DEPARTMENT 1145 ATLANTIC AVENUE ALAMEDA, CA 94501			EXAMINER BOWERS, NATHAN ANDREW	
			ART UNIT 1744	PAPER NUMBER
			MAIL DATE 08/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,555	<b>Applicant(s)</b> HUTTER ET AL.	
	<b>Examiner</b> Nathan A. Bowers	<b>Art Unit</b> 1744	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 1) Claims 9-12, 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann (US 1161984) in view of Sharpe (US 20040207840).

With respect to claims 9 and 24, Lehmann discloses a reaction vessel for processing a biological sample contained in a liquid. The vessel includes a tubular body (Figure 1:15) having a bottom wall, an upper opening (Figure 1:13) adapted for communication with a pipette, and

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sidewalls which extend between the bottom wall and the upper opening. The bottom wall and the sidewalls form a chamber (Figure 5:33) for receiving a liquid to be processed. A chip shaped carrier (Figure 2:21) having an active surface (Figure 2:32) is accessible to liquid contained in the chamber. The chip shaped carrier is located in an opening (Figure 2:18) in the sidewall of the tubular body. This is disclosed in paragraphs [0021]-[0025], [0032] and [0033]. Lehmann, however, does not expressly state that the chamber is in the shape of a cuboid having side lengths with are substantially equal.

Sharpe discloses a reaction cuvette (figure 1:26) that is used to hold a biological fluid during optical imaging. Sharpe teaches in paragraphs [0006], [0028] and [0044] that the cuvette is generally cuboid and square in cross-sectional shape.

Lehmann and Sharpe are analogous art because they are from the same field of endeavor regarding systems for processing a biological sample contained in a liquid.

At the time of the invention, it would have been obvious to modify the chamber disclosed by Lehmann so that it is in the form of a cuboid having side lengths which are substantially equal. Sharpe indicates that chambers of this shape allow one to easily detect biological analytes in a solution using an optical imaging apparatus. The use of cuboid reaction chambers is considered to be well known in the art, and it would have required only minor structural changes in the system of Lehmann to create a reaction chamber characterized with substantially equal side lengths.

With respect to claim 10, Lehmann and Sharpe disclose the reaction vessel in claim 9 wherein the tubular body is *configured and dimensioned* such that an air space exists between the

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free surface of the liquid and the upper opening. The tubular body of Lehmann is also *adapted* such that the entire active surface is in contact with the liquid contained in the chamber.

Although Lehmann does not clearly describe these limitations, the disclosed device is *configured and dimensioned* in such a way that it is capable of fulfilling these requirements.

With respect to claim 11, Lehmann and Sharpe disclose the reaction vessel in claim 9 wherein the chip shaped carrier is located at a predetermined distance from the bottom wall and from the upper opening of the tubular body. This is apparent from the Figures of Lehmann.

With respect to claim 12, Lehmann and Sharpe disclose the reaction vessel in claim 9 wherein the chip shaped carrier is transparent to enable performing electro-optical measurements of the active surface. In paragraph [0024], Lehmann indicates that the carrier is made of glass.

With respect to claims 17, 18 and 20, Lehmann and Sharpe disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above, however do not provide specific dimensions describing the volume of the reaction chamber. Regardless, it would have been obvious to ensure that the chamber was a cuboid having side lengths of at least 3 millimeters if it was determined that this volume produced the most effective results. Reaction chamber side lengths are considered result effective variables that are optimized through routine experimentation. At the time of the invention, it would have been apparent to fashion the reaction chamber disclosed by Lehmann according to the specifications presented in claims 17-

20 if it was determined that these measurements allowed the device to function at an optimum level.

With respect to claim 21, Lehmann and Sharpe disclose the reaction vessel in claim 9 wherein the active surface of the carrier has the shape of a square having side lengths between 2 to 10 millimeters. This is disclosed by Lehmann in paragraph [0034].

With respect to claims 22 and 23, Lehmann and Sharpe disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that the reaction vessel includes a removable cap. However, removable caps are considered to be notoriously well known in the art. Essentially any removable cap would be capable of interacting with the gripper of a transport mechanism.

2) Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann (EP 1161984) in view of Sharpe (US 20040207840) and Combs (US 4812294).

The combination of Lehmann and Sharpe discloses the reaction vessel as previously described above. Lehmann and Sharpe, however, do not expressly indicate that the vessel is in communication with a vessel holder capable of moving along a predetermined elliptical trajectory.

Combs discloses a system from processing a biological sample in which a reaction vessel is coupled to a vessel holder. Figure 11 and column 12, lines 14-47 state that the vessel holder is moved along a predetermined trajectory for causing mixing of fluids within the vessel. The

vessel holder is moved in a number of elliptical trajectories (Figure 11:228, Figure 11:224, Figure 11:226).

Lehmann and Combs are analogous art because they are from the same field of endeavor regarding reaction vessels.

At the time of the invention, it would have been obvious to utilize a moving means such as described by Combs to influence mixing within the reaction vessel disclosed by Lehmann. It is well established in the art that mixing means are beneficial because they allow one to provide effective contact between the sample solution and the active surface of the chip shaped carrier. The specific mixing mechanism of Combs is advantageous because it is highly reproducible, inexpensive, and more reliable than other mixing devices that are based on liquid circulation via pumping.

3) Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable Lehmann (EP 1161984) in view of Sharpe (US 20040207840) and Combs (US 4812294) as applied to claim 5, and further in view of Frackleton (US 5133937).

Lehmann, Sharpe and Combs disclose the apparatus set forth in claim 5 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that a heat transfer element is provided for heating and cooling the contents of the reaction vessel.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that comprises various heat transfer elements (Figure 1:62 and Figure 1:124). This is described in column 3, line 12 to column 4, line 48.

Lehmann, Sharpe, Combs and Frackleton are analogous art because they are from the same field of endeavor regarding biological sample processing devices.

At the time of the invention, it would have been obvious to incorporate heat transfer elements in the system disclosed by Lehmann. In column 1, lines 14-18, Frackleton indicates that biological analytical reactions are frequently temperature sensitive, and therefore require accurate temperature control. The heating and cooling mechanisms described by Frackleton are considered to be well known in the art.

4) Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable Lehmann (EP 1161984) in view of Sharpe (US 20040207840) as applied to claim 9, and further in view of Frackleton (US 5133937).

With respect to claim 13, Lehmann and Sharpe disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that the sidewall across from the chip shaped carrier is transparent.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that includes a transparent face plate (Figure 9:52) that permits visual observation of the sample.

Lehmann and Frackleton are analogous art because they are from the same field of endeavor regarding biological sample processing devices.

At the time of the invention, it would have been obvious to ensure that the sidewalls of the apparatus disclosed by Lehmann were transparent to promote visual observation of the reaction area. The use of optical detection systems that incorporate a clear, transparent window



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is considered to be well known in the art. In paragraph [0022], Lehmann suggests that the optically non-transparent sidewalls might be constructed so that they are transparent in other embodiments.

With respect to claims 14-16, Lehmann and Sharpe discloses the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that a heat transfer element is provided for heating and cooling the contents of the reaction vessel.

Frackleton discloses a system for processing a biological sample contained in a liquid. Frackleton teaches that a reaction vessel (Figure 1:90) is coupled to a vessel holder (Figure 1:30) that comprises various heat transfer elements (Figure 1:62 and Figure 1:124). This is described in column 3, line 12 to column 4, line 48.

At the time of the invention, it would have been obvious to ensure that the device disclosed by Lehmann was capable of interacting with various heat transfer elements. In column 1, lines 14-18, Frackleton indicates that biological analytical reactions are frequently temperature sensitive, and therefore require accurate temperature control. The heating and cooling mechanisms described by Frackleton are considered to be well known in the art.

5) Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lehmann (EP 1161984) in view of Sharpe (US 20040207840) as applied to claim 9, and further in view of Mochida (GB 2129551).

Lehmann and Sharpe disclose the apparatus set forth in claim 9 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly indicate that the sidewalls carry a barcode label.

Mochida discloses the use of immunoassay vessels (Figure 1:1) that utilize barcode labels (Figure 1:2) as a tracking mechanism. This is disclosed on page 3, lines 60-64.

Lehmann and Mochida are analogous art because they are from the same field of endeavor regarding biological analysis devices.

At the time of the invention, it would have been obvious to include a bar code label on the outer sidewalls of the reaction vessel disclosed by Lehmann. Bar codes are helpful in quickly sorting and tracking reaction vessels, and they can be used to immediately determine the identity of a specified reaction vessel in the presence of a plurality of otherwise identical reaction vessels, thus reducing confusion and the occurrence of mistakes.

### ***Response to Arguments***

Applicant's arguments filed 03 July 2007 with respect to the 35 U.S.C. 102 rejections involving Lehmann have been fully considered and are persuasive. Therefore, these rejection have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Lehmann and Sharpe.

The Sharpe reference addresses the deficiencies of Lehmann by indicating that cuboid reaction chambers characterized by a square cross section are known in the art. Sharpe states that cuboid reaction chambers are beneficial because they are effective in providing visual access to the fluids and analytes with the chamber cavity. As evidenced by Sharpe, the use of a cuboid

reaction chamber in the apparatus of Lehmann would not result in a configuration that would inhibit effective visualization of the active surface of the chip.

Applicant's arguments filed 03 July 2007 with respect to the 35 U.S.C. 103 rejections involving Lehmann and Vischer have been fully considered and are persuasive. Therefore, these rejection have been withdrawn. However, upon further consideration, a new ground of rejection is made in view of the combination of Lehmann and Combs.

The Combs reference clearly indicates that it is known in the art to move a reaction holder along a predetermined elliptical trajectory to encourage the mixing of fluids.

### ***Conclusion***

This is a non-final rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613.

The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



NAB

  
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SUPERVISORY PATENT EXAMINER